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**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

-----X	
ASTRAZENECA AB,	:
AKTIEBOLAGET HÄSSLE and	:
ASTRAZENECA LP,	:
KBI INC. and KBI-E INC.,	:
	:
Plaintiffs and	:
Counterclaim-Defendants,	:
	:
v.	:
	:
DR. REDDY'S LABORATORIES, LTD. and	:
DR. REDDY'S LABORATORIES, INC.	:
	:
Defendants and	:
Counterclaim-Plaintiffs.	:
-----X	

07-CV-6790 (CM)(GWG)

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**ASTRAZENECA'S REPLY TO DRL'S OPPOSITION TO
ASTRAZENECA'S MOTION TO STRIKE NEW DECLARATIONS AND ARGUMENTS
SUBMITTED WITH DRL'S SUMMARY JUDGMENT MOTION REPLY**

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I. INTRODUCTION

Ignoring once again the Court's deadlines and the Federal Rules of Civil Procedure and Evidence, DRL has submitted yet another late Declaration in an effort to patch another fatal hole in its evidence. Like the three other late Declarations, the Court should strike this Fourth Declaration of Dr. Brittain as untimely and prejudicial to AstraZeneca. The Court gave DRL plenty of time to make a complete summary judgment submission, and DRL failed to meet even the basic requirements. The Court should reject and strike all of DRL's untimely declarations and arguments, and then should deny DRL's motion for summary judgment.

DRL urges the Court to accept the new declarations as true, contrary to the holding in *Metropolitan Life Insurance Co. v. Bancorp Services LLC*, 527 F.3d 1330 (Fed. Cir. 2008) and seeks to deny AstraZeneca any chance to test the accuracy, credibility or completeness of the new Declarations. DRL argues that the new declarations "fairly met" the arguments and objections raised in AstraZeneca's summary judgment opposition, but that is not the standard for submitting new evidence and arguments on reply. Only if AstraZeneca made a completely new argument should DRL be permitted to submit new evidence. To the contrary, in this case AstraZeneca's arguments and evidence were in direct response to the "evidence" and arguments DRL submitted with its moving papers. On reply, DRL can respond to AstraZeneca's arguments, but only by relying on the evidence already of record. If the Court decides to accept DRL's reply declarations, AstraZeneca should be permitted a chance to submit a sur-reply addressing the new evidence.

II. DRL'S NEW DECLARATIONS WERE AN IMPROPER REPLY

DRL's reply declarations did not merely respond to points raised by AstraZeneca in its opposition, they completely altered and supplemented the basis for the expert opinion on which DRL's entire summary judgment motion relied. AstraZeneca has not had the opportunity

to test the soundness of DRL's conclusory assertions. For example, AstraZeneca has not deposed Dr. Brittain on his new Third and Fourth Declarations, let alone his Second Declaration submitted with DRL's summary judgment motion. Also, DRL's belated identification in the Third Brittain Declaration of its alleged ANDA and DMF evidence in its reply denied AstraZeneca the opportunity to review that alleged evidence and specifically respond to it. DRL's new arguments and declarations should be stricken, or AstraZeneca should be granted leave to file a complete sur-reply.

A. Dr. Brittain's Third Declaration Was An Improper Reply

DRL argues that simply because Dr. Brittain did not change his overall conclusions after reviewing the ANDA and DMF documents, AstraZeneca suffered no prejudice. But, Dr. Brittain completely changed the *basis* of his opinions. Federal Rule of Civil Procedure 26(a)(2)(B) requires that an expert disclose in writing the data or other information considered by the expert in forming his opinions, and for good reason – that material is essential to providing a party with a fair chance to cross-examine the expert before trial. Fed. R. Civ. P. 26(b)(4)(A). AstraZeneca has not been permitted to depose Dr. Brittain at any time, even after receiving four Declarations from him. The unfair prejudice to AstraZeneca from DRL's use of Dr. Brittain in its summary judgment motion is manifest.

1. A Summary Judgment Affidavit Cannot Rely On Inadmissible Evidence

DRL belatedly claims that even if DRL's interrogatory responses are inadmissible, Dr. Brittain's reliance on them is proper under Federal Rule of Evidence 703. That rule permits experts to rely on evidence "of a type reasonably relied upon by experts in the particular field," even if that evidence is inadmissible. Fed. R. Evid. 703. Dr. Brittain submitted a Fourth Declaration to state that experts in his field typically rely on summaries containing

certain information regarding a manufacturing process. (4th Brittain Decl. ¶ 8). AstraZeneca has had no opportunity to determine if this is true, and no opportunity to examine Dr. Brittain on this new opinion. Certainly, however, Dr. Brittain did not and cannot swear that experts in his field typically rely on unsupported summaries of scientific process data that are compiled by lawyers with no scientific credentials. DRL has produced no evidence regarding what DRL's lawyer Lee Banks may have relied on to prepare DRL's interrogatory responses, let alone any evidence that he is qualified to compile an accurate and reliable summary of DRL's manufacturing processes and test results. AstraZeneca's inability to depose Mr. Banks, the DRL lawyer who verified DRL's interrogatory responses, only compounds the prejudice faced by AstraZeneca.

Furthermore, Rule 56(e) requires that affidavits in support of a summary judgment motion shall be made on personal knowledge and shall set forth such facts as would be admissible in evidence. A court may therefore strike portions of an affidavit that are not based upon the affiant's personal knowledge, contain inadmissible hearsay or make generalized and conclusory statements. *Hollander v. American Cyanamid Co.*, 172 F.3d 192, 198 (2d Cir. 1999). Dr. Brittain's Second, Third and Fourth Declarations suffer from all three flaws. At the time of his Second Declaration, Dr. Brittain admittedly had no personal knowledge of DRL's ANDA and DMF documents, and the entire declaration was based on inadmissible hearsay. Dr. Brittain's Third and Fourth Declarations make conclusory statements, including altering the entire basis of Dr. Brittain's opinion with no detailed expert explanation of this new evidence on which he now relies. Courts are free to disregard any factual assertions that are not supported by admissible factual support. *Epstein v. Kemper Ins. Co.*, 210 F.Supp.2d 308, 314 (S.D.N.Y. 2002); *See Pharmacy, Inc. v. American Pharmacy Partners, Inc.*, No. 05-776, 2007 U.S. Dist. LEXIS 74384, *2 n.2 (E.D.N.Y. Sept. 14, 2007). This is precisely what this Court should do,

and it should strike Dr. Brittain's belated attempt to add some new allegedly admissible factual support to bolster his opinions.

2. DRL's Answer To Interrogatory No. 10 Is Not Admissible Under Rule 1006

DRL's attempt to characterize its lawyer's alleged description of the manufacturing processes as a Rule 1006 summary is specious. Rule 1006 states that "the contents of voluminous writings, recordings, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation." Fed. R. Evid. 1006. The documents in the current case are not so voluminous that they cannot easily be examined by the Court. AstraZeneca's expert, Dr. Luk, cited to relevant portions of DRL's ANDA and DMF to support his conclusions regarding DRL's product and processes. *See Daniel v. Ben E. Keith Co.*, 97 F.3d 1329, 1335 (10th Cir. 1996) (refusing to admit summary of evidence that is not voluminous, already admitted and available for use, and used by the defendant without difficulty in its unsummarized form). Resort to Rule 1006 cannot wipe away the fact that DRL never referred to any evidence regarding its processes or product to support its motion.

DRL's Answer to Interrogatory No. 10 is also not admissible as a summary because it was not identified as such at the time it was presented, and the summary was not compiled by a qualified expert. *In re E.I. Du Pont De Nemours & Co.*, 918 F. Supp. 1524, 1545 (M.D. Ga. 1995), *rev'd on other grounds* 99 F.3d 363 (11th Cir. 1996) (proponent of summary must invoke and rely on Rule 1006); *U.S. ex rel Maris Equipment Co., Inc. v. Morganti, Inc.*, 163 F.Supp.2d 174, 201-02 (E.D.N.Y. 2001) (party seeking to use a summary under Rule 1006 must identify the exhibit as such and provide a list or description of the documents supporting the exhibit). DRL attempted to classify the interrogatory answer as a Rule 1006 summary for the

first time in its opposition to AstraZeneca's motion to strike, well after Dr. Brittain relied on the answer in his Second Declaration.

Furthermore, Mr. Banks is an attorney, not a pharmaceutical manufacturing process expert, and cannot confirm the accuracy of the process description in DRL's interrogatory responses. The interrogatory responses are therefore inadmissible regardless of whether they are classified as a "summary" because they contain scientific and technical conclusions from an unqualified expert. Fed. R. Evid. 701, 702; *Lifewise Master Funding v. Telebank*, 374 F. 3d 917, 928-30 (10th Cir. 2004); *E.g., Brazier v. Harsbro, Inc.*, No. 99 Civ. 11258, 2004 U.S. Dist. LEXIS 4064, *23-24 (S.D.N.Y. Mar. 9, 2004). The interrogatory response also contains "scientific, technical, or other specialized knowledge" that Rule 701 expressly prohibits a lay person from testifying to. *E.g., Weschler v. Hunt Health Sys., Ltd.*, 198 F. Supp. 2d 508, 528-29 (S.D.N.Y. 2002). Rule 1006 does not excuse these other evidentiary flaws in DRL's response to Interrogatory No. 10.

As a result, despite DRL's belated attempt to re-characterize its Answer to Interrogatory No. 10, it remains conclusory, inadmissible hearsay, which was improper as the basis for Dr. Brittain's Second Declaration in support of DRL's motion for summary judgment.

B. The Declaration Of Dr. Kumara Sekar Was An Improper Reply To AstraZeneca's Opposition

DRL must have known that a case-dispositive motion cannot be based solely on inadmissible interrogatory responses and lawyer argument. The Sekar Declaration's attempt to correct this fatal error by the wholesale reference to unspecified large chunks of DRL's ANDA and DMF would be insufficient if timely, and should not be considered on reply.

DRL's introduction of these documents does nothing to support DRL's reply arguments. For example, nothing in DRL's reply discusses whether the XRPD data in its ANDA

and DMF supports the claims in its interrogatory answers that its ANDA Product does not contain highly crystalline material. Moreover, the DMF and ANDA documents are not explained at all, making it impossible for AstraZeneca or the Court to understand what page or information in them might relate to DRL's arguments.

DRL is incorrect that a deposition of Dr. Sekar is unnecessary. A deposition would permit AstraZeneca to learn whether other portions of the ANDA and DMF support or contradict DRL's claims regarding its product. A deposition could also assist AstraZeneca in ascertaining whether the produced portions of the ANDA and DMF accurately and fully describe the product DRL intends to market if it obtains FDA approval. Dr. Sekar did not even swear that the produced ANDA and DMF documents are complete and up to date, or that they accurately describe DRL's ANDA and DMF products and processes. Fairness demands that the Sekar Declaration be struck.

C. The Third Declaration Of Louis H. Weinstein Raises New Facts That Are Not Appropriate On Reply

The Third Declaration of Louis H. Weinstein did not just respond to AstraZeneca's opposition papers, it introduced new statements of fact to which AstraZeneca had no opportunity to respond. Local Rule 56.1 permits a moving party to submit a statement of facts. It also provides for the non-movant to respond to each of those facts. DRL attempts to avoid the mandatory responsive nature of Rule 56.1 by belatedly and incorrectly summarizing conversations with AstraZeneca's counsel through another hearsay Declaration of its own counsel. If the facts in Mr. Weinstein's Third Declaration were allegedly material, DRL should have attempted to supplement its Rule 56.1 Statement. It did not. His new inaccurate summaries are prejudicial to AstraZeneca and should be stricken.

III. CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that the Court strike DRL's Declaration of Kumara Sekar, Third Declaration of Louis H. Weinstein, Third Declaration of Harry G. Brittain, and Fourth Declaration of Harry G. Brittain and all arguments relying on this new evidence, submitted with DRL's reply to AstraZeneca's opposition to DRL's summary judgment motion. Alternatively, if the Court is inclined to consider DRL's new Declarations, AstraZeneca respectfully requests leave to file a sur-reply so that it may substantively address DRL's belated facts and arguments.

Date: September 11, 2008

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CERTIFICATE OF SERVICE

I certify that on this 11th day of September 2008, I caused a true and correct copy of the foregoing **ASTRAZENECA'S REPLY TO DRL'S OPPOSITION TO ASTRAZENECA'S MOTION TO STRIKE NEW DECLARATIONS AND ARGUMENTS SUBMITTED WITH DRL'S SUMMARY JUDGMENT MOTION REPLY** be served upon counsel for DRL in the following manner:

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